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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,976

11/20/2003

Syed F.A. Hossainy

50623.317

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03/10/2008

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/718,976	Applicant(s) HOSSAINY ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/03/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-12,15-21,23-30 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,15-21,23-30 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/03/2008 has been entered.

The amendments to the claims filed 09/18/2007 has been entered, claims 1-3, 5-21 and 23-36 are pending, previously claims 13-14 and 31-32 have been withdrawn. Any rejection from the previous office action not addressed below has been withdrawn.

The terminal disclaimer filed on 09/18/2007 disclaiming the terminal portion of any patent granted on this application which has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 09/18/2007, with respect to claims 15 and 33 have been fully considered and are persuasive. The rejection of claims 15 and 33 has been withdrawn.

Claims 1-3,5-12,15-21,23-30,33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claims 1 and 19 recite that the hydrolyzed poly(lactic acid) PLA or the block copolymer have two terminal hydroxyl groups. The examiner could find no support within the specification for this new limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5-12 and 15-21, 23-30 and 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (US 6,258,121 B1, cited previously) and the teachings of Kim et al (US 5,548,035, cited previously) incorporated by reference.

Yang teaches a stent having a polymeric coating for controllably releasing an included active agent, the coating comprises polymeric materials and blends thereof

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selected from polymers such as polycaprolactone (PCL), polyhydroxybutyrate (PHB), poly(lactide-co-glycolide) and preferably PLA-PEO copolymer for example. See abstract, col 4 lin 4-22. Regarding the limitation that the PLA-PEO copolymer is a triblock, Yang incorporates by reference the PLA-PEO copolymers of Kim et al (US 5,548,035) who teaches the use of PLA-PEO-PLA blocks. See col 5 lin 5-7. Kim's copolymers also meet applicants claimed integer range for n and m in claims 10, 12, 28 and 30. Regarding applicants limitations for the MW of the hydrolyzed polymer, Yang incorporates by reference the PLA-PEO copolymers of Kim who teaches the length of the PLA polymers can be from 20-500, it is inherent that within this broad range applicants claimed MW range is met, for instance a PLA polymer with 20 monomer units would have a MW ~1400-1500, 200 monomer units would be ~14,000-15,000. Regarding the limitations that PLA is hydrolyzed, this limitation does not give the claim any patentable distinction from Yang. By further processing the copolymers by hydrolysis applicants are essentially shortening the PLA segments by degrading them, therefore the copolymers will essentially have a range of different sized PLA units. This is not seen as being patentably distinct from Yang's copolymers synthesized by coupling PEG to PLA, in which PLA is synthesized or purchased from a commercial source will have numerous lengths with varying molecular weights, therefore the additional treatment claimed by applicants does not give the claim any patentable distinction from the Yang reference. Both methods to make the copolymer would essentially result in PLA blocks of varying lengths, therefore the claimed invention is the same because the claims are to a medical article not the method to process the PLA

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polymers. Regarding the new limitation that the PLA polymer or a block-copolymer would have two hydroxyl terminal groups, Yang teaches the use of PLA-PEO copolymers, the end terminus of this block copolymer will contain two hydroxyl groups. For instance PLA $\text{H}-(\text{-OCH}(\text{CH}_3)\text{-CO-})_n\text{-OH}$ would react by condensation with PEO $\text{H}-(\text{-OCH}_2\text{CH}_2\text{O-})_n\text{-H}$ to form PLA-PEG, $\text{H}-(\text{-OCH}(\text{CH}_3)\text{-CO-})_n-(\text{-OCH}_2\text{CH}_2\text{O-})_n\text{-H}$, note the copolymer has two terminal hydroxyl groups. Furthermore it is noted by the examiner that any PLA polymer can be considered to have two terminal hydroxyl groups since PLA is $\text{H}-(\text{-OCH}(\text{CH}_3)\text{-CO-})_n\text{-OH}$, note there are two hydroxyl functional groups present on the ends of the polymer.

Response to Arguments

Applicant's arguments filed 09/18/2007 have been fully considered but they are not persuasive. Applicants assert that Yang does not teach a hydrolyzed PLA that has two terminal hydroxyl groups.

The relevance of this assertion is unclear. The reasoning for why Yang still anticipates applicants claimed hydroxyl terminated PLA is recited above and incorporated herein. The PLA-PEO copolymers of Yang have two hydroxyl end units, therefore applicants limitations are met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3,5-12,15-21,23-30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 6,258,121 B1, cited previously) in view of Okada et al. (US 6,113,943, cited previously).

Yang is disclosed above.

As noted above Yang does not disclose a hydrolyzing treatment of the PEO-PLA copolymers to be incorporated into the stent coating, however this limitation does not make the claims patentably distinct from Yang. By further processing the copolymers by hydrolysis applicants are essentially shortening the PLA segments by degrading them, therefore the copolymers will essentially have a range of different sized PLA units. This is not seen as being patentably distinct from Yang's copolymers synthesized by coupling PEG to PLA, in which PLA is synthesized or purchased from a commercial source will have numerous lengths with varying molecular weights, therefore the

additional treatment claimed by applicants does not give the claim any patentable distinction from the Yang reference. However if the claims are read so that the limitation of a hydrolyzed PLA polymer is part of the method for fabricating the medical article, the limitation as disclosed below would still be obvious.

Okada is used only for the disclosure within that it was advantageous to hydrolyze a polylactic acid for sustained release preparations. The disclosed advantage was that the hydrolyzed lactic acid provided a sustained release preparation with a small initial burst of active ingredient, this is in contrast to polylactic acid formed from ring-opening polymerization in which the sustained release provided a large initial burst. The skilled artisan could foresee from the disclosures of Yang and Okada that PLA-PEG-PLA copolymers would also be susceptible to a hydrolyzing step, this is obviously so because PLA block is the same thus one would expect the same effect upon hydrolysis.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Yang discloses all of applicants claimed invention except a hydrolyzing treatment processing step of the PEO-PLA copolymers of the stent coating, while Okada disclosed hydrolyzed PLA was already known in the art at the time of the invention. The motivation to combine the above documents would be to provide a coated stent with a block copolymer comprising hydrolyzed PLA that would provide a sustained release of a bioactive agent. The advantage of such a stent coating would be that the hydrolyzed lactic acid would provide a sustained release with a small initial

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burst of active ingredient. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion


No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

<div><i>Application Number</i></div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/718,976	HOSSAINY ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	